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Group Art Unit: 3739
Docket No.: 151P11200US01

REMARKS

Claims 1, 6 – 9 and 13 – 24 are pending in this application.

Claims 1 and 6 – 8 have been amended.

Claims 2 – 5 and 10 – 12 have previously been canceled.

Claims 1 – 15 have been rejected.

Claims 16 – 24 are new.

No claims have been allowed.

Amendments to the Claims

Independent claim 1 has been amended to clarify the diameters of the catheter and stylet. Claim 1 has been amended in lines 1 – 3, 6 – 8 and 10 – 12 in order to relate the hemispherical shape of the tip of the second end of the stylet to the outside diameter of the catheter, rather than to the diameter of a hole in the dura of a patient. Claim 1 now requires that a hemispherical diameter of the tip of the second end of the stylet be not greater than the outside diameters of the catheter. In particular, claim 1 has been amended in line 1 to delete "of a first predetermined diameter"; in lines 2 – 3, deleting "a second predetermined" and adding "an outside" before "diameter"; and in lines 6 – 8 to delete "with a diameter approximately equal to said first predetermined diameter" and adding "having a hemispherical diameter not greater than said outside diameter of said catheter." Support for these amendments is provided in paragraph [45] and Fig. 7 of the specification. No new matter has been added.

Claims 6 – 8, all ultimately dependent upon claim 1, have been amended to be consistent with the above-described amendment to claim 1. Claims 6 – 8 have all been amended on lines 1 – 2 for consistent referral to "outside diameter" of the catheter and to the "hemispherical diameter" of the tip of the stylet. Claim 8 has also been amended in line 2 to correct a typo by

deleting the redundant "percent" and in line 3 to delete "second." Support for these amendments is provided in claim 1 and in paragraph [45] of the specification. No new matter has been added.

New independent claim 16 describes a stylet which has which has a hemispherical tip wherein a flat surface of the hemispherical tip is oriented towards the second end of the stylet and the rounded surface is oriented away from the second end of the stylet, making the flat surface most distal. New claim 16 is supported by Fig. 7 and paragraphs [45 – 46] of the specification. No new matter has been added.

New claims 17 – 20, all dependent on claim 16, additionally specify the relationship of the hemispherical diameter of the hemispherical tip of the stylet to the outside diameter of the catheter. New claims 17 – 20 are supported by claims 1, 6 – 8 and paragraphs [45 – 46] of the specification. No new matter has been added.

New claim 21, dependent on claim 1, specifies the relationship of the outside diameter of the catheter in a stretched state and a relaxed state, to the hemispherical diameter of the tip of the stylet, respectively. New claim 21 is supported by paragraphs [45 – 46] of the specification. No new matter has been added.

New claims 22 – 24, dependent on claim 9, specify the steps for stretching the catheter so that the diameter of the catheter shrinks so that it is smaller than the hole in the dura, the catheter is inserted into the hole in the dura, and then relaxed into a relaxed state. New claims 22 – 24 supported by paragraphs [45 – 46] of the specification. No new matter has been added.

Rejections Under 35 USC § 112

Claims 1-15 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These rejections over claims 1 – 8, as amended, and claims 9 – 15, as amended, are respectfully traversed.

Independent claim 1 has been amended to remove any comparison of the hemispherical shape of the tip of the second end of the stylet to the diameter of the hole in the dura. Instead, amended claim 1 now requires that the hemispherical diameter of the hemispherical shape of the tip of the second end of the stylet be related to the outside diameter of the catheter. Since both of these dimensions are easily determined solely by reference to the apparatus, and without reference to the hole in the dura of a patient, the claimed apparatus is particularly pointed out and distinctly claimed as required by 35 U.S.C. § 112, second paragraph. With this amendment, the rejection of claim 1 under 35 U.S.C. § 112, second paragraph, should be cured.

Claims 6 – 8, all ultimately dependent upon claim 1, have also been amended to be consistent with the amendment made to claim 1 and, in particular, to remove any comparison of hemispherical shape of the tip of the second end of the stylet to the diameter of the hole in the dura. Following the same logic as applied above with respect to claim 1, claims 6 – 8 should also now particularly point out and distinctly claim the apparatus as required by 35 U.S.C. § 112, second paragraph. With the amendment of claim 1 and these amendments to claims 6 – 8, the rejection of claims 6 – 8 under 35 U.S.C. § 112, second paragraph, should be cured.

The rejection of claim 9 under 35 U.S.C. § 112, second paragraph, is respectfully traversed. Claim 9 describes a method for creating a hole in the dura of a particular, predetermined size. Thus, the meets and bounds of the claim are not unclear, because the purpose of the method is to create a hole of a particular size. The diameter of the hole in the dura may be easily determined during the performance of the method steps. Hence, the recitation to the diameter of the hole in the dura is neither vague nor indefinite. Thus, it is respectfully submitted that the rejection of claim 9 under 35 U.S.C. § 112, second paragraph, is improper and should be withdrawn. Because the rejection of claim 9 under 35 U.S.C. § 112, second paragraph, is improper, it is respectfully submitted that the rejections of dependent claims 13 – 15 are also improper and should be withdrawn.

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Rejections Under 35 USC § 102(e)

Claims 1 and 6-8 have been rejected under 35 USC § 102(e) as being anticipated by U.S. Patent No. 6,761,718, Madsen et al ("Madsen et al '718"). These rejections are respectfully traversed.

Madsen et al '718 discloses a bipolar coagulator that can be passed through the internal lumen of a ventricular catheter previously implanted into a cranial ventricle of a living subject and engaged in-situ. The bipolar coagulator can provide bipolar electrical arc currents for coagulation cauterization of adherent brain tissues, such as the choroids plexus, which occludes fluid flow into the intake drainage holes in the implanted ventricular catheter.

The bipolar coagulator has a proximal end adapted to be inserted through the lumen of an already inserted ventricular catheter. The bipolar coagulator has two electrodes intended to coagulate adherent brain tissues, such as the choroids plexus, which otherwise would occlude ports in the sidewall of the catheter. Thus, the sole intended purpose of the bipolar coagulator is to clear ports in an already-inserted in-vivo ventricular catheter.

Claim 1 requires a catheter with a lumen, a stylet with a first end for insertion into the lumen of the catheter, a second end with a hemispherical tip and a hemispherical diameter not greater than the outside diameter of the catheter, and a means for applying an electrical current. The apparatus described in claim 1 allows the user to create a hole in the dura the same diameter as the stylet with little of the stylet passing through the dura, significantly reducing the possibility of injury to the brain compared with a more elongated tip.

Madsen et al '718 does not show, disclose or suggest a stylet with a hemispherical tip. Nor does Madsen et al '718 show, disclose or suggest the relationship wherein the hemispherical diameter is not greater than the outside diameter of the catheter. In fact, the embodiments shown in Madsen et al '718 suggest only that the stylet be used within a catheter to remove tissue that is blocking a hole in the side wall of the catheter. (*See e.g.* column 6, lines 47 – 49) Thus there is

no reason for Madsen et al '718 to disclose a stylet with a hemispherical tip and a hemispherical diameter that is not greater than the outside diameter of the catheter.

Claim 1 explicitly requires a stylet having a second end formed with a tip having a hemispherical shape. The hemispherical shape is required to have a hemispherical diameter not greater than the outside diameter of the catheter.

There is no disclosure in Madsen et al '718 that discloses such a geometrical relationship. Further, the apparatus disclosed in Madsen et al '718 does not even show a tip with a hemispherical shape having a hemispherical diameter. Rather Madsen et al '718 discloses only a coagulator having a rather pointed tip having no discernable geometrical relationship to the outside diameter of the catheter.

Thus, it is respectfully submitted that Madsen et al '718 does not disclose the explicitly claimed structure of the apparatus of claim 1 and the rejection of claim 1 under 35 U.S.C. 102(e) over Madsen et al '718 is improper and should be withdrawn.

Claims 6 – 8 are dependent on claim 1, and thus have all of the limitations of claim 1. Because the rejection of claim 1 under 35 U.S.C. 102(e) is improper, it is respectfully submitted that the rejection of claims 6 – 8 under 35 U.S.C. 102(e) over Madsen et al '718 are also improper and should be withdrawn.

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Summary

In view of the amendments made and the arguments presented, claims 1, 6 – 9 and 13 – 15 should be allowable, this application should be in condition for allowance and a notice to that is earnestly solicited.

Respectfully submitted,

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